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EXAMINER
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WOODALL, NICHOLAS W

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/532,909  
Filing Date: December 16, 2005  
Appellant(s): FRIGG ET AL.

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Oleg F. Kaplun  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed August 3<sup>rd</sup>, 2009 appealing from the Office action mailed November 18<sup>th</sup>, 2009.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5,032,125	Durham	7-1991
2,454,813	Lawes	10-1995

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6,648,889	Bramlet	11-2003
4,432,358	Fixel	2-1984
5,908,422	Bresina	6-1999
6,187,007	Frigg	2-2001

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 19-25, 27, 31, 34-38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S. Patent 5,454,813).

Durham discloses a device comprising an intramedullary pin (20), a bone fixation element (60), a sliding sleeve (40), and a locking mechanism (90). The intramedullary rod includes a first longitudinal axis, a proximal portion, a distal portion, and at least one transverse opening through the proximal portion of the pin. The transverse opening forms an oblique angle with the first longitudinal axis of the pin. The bone fixation element includes a second longitudinal axis, a first end, a second end, and a shaft. The sliding sleeve includes a central bore, an interior profile, and an exterior profile surface. The bone fixation device, sliding sleeve, and the locking mechanism are capable of

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being inserted through the transverse opening while assembled. The bone fixation element further includes a threaded longitudinal bore at the second end of the element. The locking mechanism is a fixing screw having a screw head has a diameter larger than the diameter of the threaded shank. The outside thread of the fixing screw corresponds to the threaded bore of the bone fixation element. The bone fixation element is axially fixed relative to the sliding sleeve. The rear end of the sliding sleeve extends past the second end of the bone fixation device at least 0.01 mm. The first end of the bone fixation element includes a screw thread. The locking mechanism is capable of limiting the axial displacement of the sliding sleeve relative to the intramedullary pin. The bone fixation element is a screw. Durham fails to disclose a device wherein the interior surface profile of the sliding sleeve is configured to permit free rotation of the bone fixation device relative to the sleeve and the transverse bore of the intramedullary pin having a non-circular cross-section (claims 19 and 37) and the exterior profile of the sliding sleeve having a cross-section complimentary to the cross-section of the transverse bore (claim 37). First, Durham does disclose that the interior surface profile of the sliding sleeve may include flat surfaces and the outer surface profile of the bone fixation device includes complementary flat surfaces, but Durham discloses that is a preferred embodiment and is not necessary for the invention to operate properly. Therefore, if the flat surfaces were to be omitted from the sliding sleeve and the bone fixation device, the interior surface profile of the sliding sleeve could have a circular cross-section and the outer surface profile of the bone fixation device could have a circular cross-section, which would permit the bone fixation element to rotate freely

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relative to the sliding sleeve. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to manufacture the interior surface profile of the sliding sleeve and the outer surface profile of the bone fixation of Durham with a circular cross-section, since appellant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing an interior surface profile of a sliding sleeve and the outer surface profile of a bone fixation element. In re Dailey and Eilers, 149 USPQ 47 (1966). Lawes teaches a device wherein the cross-section of a transverse bore is non-circular and complementary to the exterior profile of a sliding sleeve in order to prevent rotation of the sliding sleeve relative to an intramedullary pin and to allow the sleeve to slide axially within the transverse bore (column 3 lines 62-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Durham with a transverse bore having a non0circular cross-section that is complimentary to the exterior profile of the sliding sleeve in view of Lawes in order to prevent rotation of the sliding sleeve relative to an intramedullary pin and to allow the sleeve to slide axially within the transverse bore.

3. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S. Patent 5,454,813) further in view of Bramlet (U.S. Patent 6,648,889).

The combination of Durham as modified by Lawes disclose the invention as claimed except for the bone fixation element having a first annular groove and the

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internal surface of the sliding sleeve having a second annular groove, which are engaged by a ring element. Bramlet teaches a device that includes a nail element with a bore and a locking element with annular groove, which are engaged by a ring element in order to detent the axial movement of the locking element in the bore of the nail element (column 8 lines 32-53). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the combination of Durham as modified by Lawes wherein the sleeve and bone fixation element of Durham as modified by Lawes with annular grooves and a ring element in view of Bramlet in order to detent axial movement of the bone fixation element in the sleeve.

4. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S. Patent 5,454,813) further in view of Fixel (U.S. Patent 4,432,358).

The combination of Durham as modified by Lawes discloses the invention as claimed except for the bone fixation element comprising an externally threaded portion at the second end (claim 28) and the locking mechanism including a nut with an internal thread (claim 29). Fixel teaches a device comprising a bone fixation element having external threads at a second end of the element and a locking mechanism including a nut having internal threads in order to engage the nut (column 3 lines 50-52) and to compress the broken portions of bone (column 2 lines 63-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the combination of Durham as modified by Lawes with a bone fixation element having external threads at the second end of the element and a locking mechanism

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which includes a nut with internal threads in view of Fixel in order to engage the nut and to compress the broken portions of bone.

5. Claims 30, 32, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S. Patent 5,454,813) further in view of Bresina (U.S. Patent 5,908,422).

The combination of Durham as modified by Lawes discloses the invention as claimed except for the bone fixation element including a plurality of helical blades. Bresina teaches a bone fixation element comprising a plurality of helical blades in order to minimize the tendency to cut through the cancellous bone tissue after implantation and provides the required stiffness to maintain a relative orientation of the bone fragments (column 2 lines 15-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Durham as modified by Lawes with a bone fixation element including a plurality of helical blades in view of Bresina in order to minimize the tendency to cut through the cancellous bone tissue after implantation and provides the required stiffness to maintain the relative orientation of the bone fragments.

6. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S. Patent 5,454,813) further in view of Bresina (U.S. Patent 5,908,422) further in view of Frigg (U.S. Patent 6,187,007).

The combination of Durham as modified by Lawes further modified by Bresina disclose the invention as claimed except for the helical blades having a pitch of at least 50 mm. Frigg teaches a bone fixation element wherein the helical blades have a pitch of



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at least 50 mm in order to not allow any torque to be transmitted to the femur head (column 2 lines 4-7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Durham as modified by Lawes further modified by Bresina with a bone fixation element comprising helical blades with a pitch of at least 50 mm in view of Frigg in order to not allow any torque to be transferred to the femur head.

#### **(10) Response to Argument**

7. The applicant's argument that the Durham reference does not disclose an embodiment wherein the sliding sleeve has a central bore with an interior surface profile, wherein the interior surface profile is configured to receive the shaft of the bone fixation element within the sleeve while permitting free rotation of the bone fixation element relative to the sleeve is not persuasive. First, the examiner would like to state that a reference may explicitly, implicitly, or inherently disclose elements of a device. An implicit disclosure is a suggested that is not explicitly disclosed, but is an embodiment that could be used as suggested by the reference. As discussed in the previous actions Durham discloses a preferred embodiment that comprises flat surfaces to prevent rotation of the lag screw (column 2 lines 55-63 and column 3 lines 17-19). It is extremely clear by the disclosure that the embodiments shown in the figures and discussed in the disclosure are the preferred embodiments and do not encompass all the variations of the invention. As stated in column 2 lines 58-63, Durham implicitly discloses, "the sleeve **may include an engaging surface** formed on the interior of the sleeve and adapted for cooperation with complementary engaging surface formed on the body member of the

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lag screw to prevent rotation of the lag screw within the sleeve” (emphasis added by the examiner). Durham simply states that the device may include engagement surfaces to perform the function if one so desired, which means Durham implies or suggests that the device does not have to include the engagement surfaces and therefore the engagement surfaces may not be included in the device. The engagement surfaces are not disclosed as being critical to the function of the device and are capable of being modified without destroying the reference as suggested by Durham in the reference. Therefore, if the flat engagement surfaces were omitted the interior surface of the sleeve could have a circular cross-section permitting the screw to rotate freely within the sleeve. Durham simply states that the device may include engagement surfaces to perform the function if one so desired, which means that the device does not have to include the engagement surfaces and therefore may not be included in the device. Therefore, the surfaces may be modified in a way consistent with the knowledge of one of ordinary skill in the art without preserving the function because the structure and the function are not critically required to be included in the invention. The applicant’s argument that assuming engaging surfaces (44 and 66) are not required by the disclosure of the reference is the use of improper hindsight is not persuasive. Any judgment of obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. As long as judgment of obviousness takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant’s disclosure, such a reconstruction is proper. In re McLaughlin, 443 F.2d 1392; 170

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USPQ 209 (CCPA 1971). Durham clearly suggests that an embodiment of the device does not include the engagement surfaces as discussed above. Therefore, the examiner is using knowledge from the reference and not knowledge only gleaned from the applicant's disclosure. Since knowledge provided by the Durham reference was known in the art at the time the invention was used the examiner did not use hindsight reasoning and the judgment of obviousness is proper. The appellant further argues that the examiner's statement that Durham's device may not include the engagement surfaces is based on flimsy support that cannot be used to justify the structural changes proposed by the examiner (see page 8 lines 1-12. This argument is not persuasive. As discussed above, disclosure within a reference can be explicit, implicit, or inherent as discussed by the MPEP. The Durham reference clearly implies that the engagement surfaces do not need to be provided in the device and therefore implicitly discloses an embodiment that does not include the engagement surfaces. The remaining arguments are based on the concepts of the arguments for claims 19 and 37 as discussed above.

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**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Nicholas Woodall/

Examiner, Art Unit 3775

Nicholas Woodall

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